

REMARKS

Upon entry of the above amendment, claims 1, 4, 5, 6, 7, 13, 19, 20, 80, 84, 85, 91 and 95 will be pending in this application. Claims 12, 87, 89, 90, 92 and 94 have been canceled without prejudice. Claim 1 has been amended to incorporate the elements of claim 12; and to delete the term “antisense” and the phrases “in dosage form suitable for non-parenteral administration” and “wherein said antisense oligonucleotide modulates expression of a cellular adhesion protein, modulates a rate of cellular proliferation, or has biological activity against eukaryotic pathogens or retroviruses”. Claim 1 as presented in the above Listing of Claims is referred to hereinafter as “amended claim 1.” Amended claim 1 is fully supported by the specification, at, for example, page 3, lines 5-19, page 13, lines 33-36, and page 15, lines 10-25. No new matter is added.

As a preliminary matter, the Advisory Action listed the claims rejected as being claims 1, 4-7, 10, 12, 13, 15, 17, 19, 20, 80, 84, 85 and 87-96. However, Applicants note that claims 15, 17, 88, 93 and 96 were previously canceled. See Response filed on November 24, 2003. Thus, Applicants will not address claims 15, 17, 88, 93 and 96 in this Response.

Applicants also wish to thank Examiner Epps Ford for the courtesy shown in an interview with Applicants’ representatives on February 4, 2004, in which the Examiner indicated that claim 1 would be looked upon favorably if it were amended to recite specific bile salts. Accordingly, for the sole purpose of compact prosecution, Applicants have amended claim 1 to include specific bile salts. As such, Applicants assert that the amended claim 1, and all other pending claims (which depend therefrom) are free from prior art and are in condition for allowance. Nevertheless, Applicants respectfully assert that the previously presented claim 1 complies fully with the patent laws. For example, the previously presented claim 1 (and dependent claims 5, 6, 7, 10, 17, 19, 20) were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by unexamined Japanese Patent Application No. 7-330614 (hereinafter “Kawai”). In particular, the Office Action

alleged that the agent "polyoxyethylene-(20)-ether" is a bile salt as recited in claim 1. Applicants note, however, that the Office Action has provided no basis for this allegation. As the present specification indicates, a bile salt of the present invention is effective as a penetration enhancer. See the specification, page 15, lines 3-5. The Office Action, in contrast, has not shown that the "polyoxyethylene-(20)-ether" reported in Kawai is effective as a penetration enhancer. Further, contrary to the allegation by the Office Action, Kawai fails to teach or suggest a composition in "dosage form." The term "dosage form" is defined by the specification as one in which the components of the composition are "uniformly" distributed. For example, the specification defines a formulation in dosage form as formulation that is

prepared by uniformly and intimately bringing into association the active ingredients with liquid carriers or finely divided solid carriers, or both, and then if necessary, shaping the product.

Specification at page 58, lines 9-14. Kawai is devoid of any information regarding a composition being in a dosage form. Accordingly, Applicants respectfully submit that Kawai cannot anticipate the claims under 35 U.S.C. § 102(b).

Further, prior to the present amendment of claim 1, claims 1, 4-7, 15 and 84 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Pat. No. 5,980,861 (hereinafter "Hnatowich"), on the basis that Hnatowich at column 18, lines 50-67, discloses a bile salt of the present invention. However, the Office Action has not indicated which compound it considers to be a bile salt of the present invention. For example, the Office Action has not shown which compound reported in Hnatowich may be effective as a penetration enhancer.¹ Thus, Applicants respectfully maintains that Hnatowich fails to disclose, teach or suggest the inclusion of "bile salts" in the composition. Accordingly, Applicants respectfully assert that Hnatowich cannot anticipate claim 1 under 35 U.S.C. § 102(e).

¹ To the extent that the Office Action may have intended to assert that the "choline" listed on column 18 is a "cholic acid" identified by the specification as a bile salt, Applicants respectfully point out that a choline (a 2-(trimethylammonium)ethanol) is a molecule that is completely different from a cholic acid (steroidal molecule); and that choline is not a bile salt.

Claims 87-96 were under 35 U.S.C. §102 (a) as allegedly being anticipated by WO 97/13528 (hereinafter "Nielson"). For the sole purpose of compact prosecution, Applicants have cancelled claims 87, 89, 90, 92 and 94, rendering moot the rejection. Nevertheless, Applicants respectfully assert that claim 87 complies fully with the patent laws. For example, the Office Action alleged that the compound "polyoxyethylene sorbitan ester" reported in Nielson is a bile salt recited in claim 87. Applicants note, however, that the Office Action has provided no basis for this allegation. As the present specification indicates, a bile salt of the present invention is effective as a penetration enhancer. Specification at page 15, lines 3-5. The Office Action, in contrast, has not shown that the "polyoxyethylene sorbitan ester" is effective as a penetration enhancer. Thus, Nielson cannot anticipate claim 87, or those claims depending therefrom.

As discussed above, claims 88, 93 and 96 were cancelled in an earlier Response.

Amended claim 91 and claim 95 depend from amended claim 1, and are patentable for at least the same reasons as those regarding amended claim 1.

In view of the foregoing, Applicants submit that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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